UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/476,415	12/30/1999	DALE SANDBERG	3855.29	7821

21999 7590 07/15/2003

KIRTON AND MCCONKIE
1800 EAGLE GATE TOWER
60 EAST SOUTH TEMPLE
P O BOX 45120
SALT LAKE CITY, UT 84145-0120

EXAMINER	
BLECK, CAROLYN M	
ART UNIT	PAPER NUMBER
3626	

DATE MAILED: 07/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/476,415	SANDBERG, DALE	
	Examiner	Art Unit	
	Carolyn M Bleck	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29 and 31-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29 and 31-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the RCE filed 24 April 2003. Claims 1-29 and 31-41 are pending. Claim 30 has been cancelled. Claims 21, 24-25, 27-28, 31-33, 36-37, and 40 have been amended. Claim 41 is newly added.

Specification

2. At pages 9-10 of the response filed 24 April 2003, Applicant argues that "a dynamically customizable form" does not constitute new matter, and furthermore provides portions of the specification to clarify the issue and to specifically point out support for the limitation in the originally filed disclosure.

In response, the Examiner respectfully submits that Applicants arguments are not persuasive and the objection under 35 U.S.C. 132 is maintained. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

The recitation of "a dynamically customizable form" constitutes new matter. In particular, Applicant points to the following portions of the specification as support for the recitation of a "dynamically customizable form":

a) a form is used to keep a patient record of the procedures performed and diagnosis given by a healthcare provider and/or at a particular facility (page 5 lines 19-20, page 5 lines 4-6, and page 9 lines 20-22);

(b) the form is "customized to reflect specialties provided in that office" (page 5 lines 11-12), the form reflects procedures depending on the type of patient (page 11 lines 6-10) and/or the form reflects procedures depending on the type of provider (page 11 lines 6-10); and

(c) the records can be generated in a real time setting (page 5 line 7), the objects on the form are selectable by a user (page 17 line 23 to page 18 line 24), and/or the form provides the first characters of a code positions the selectable entries closer to the desired code (page 17 line 23 to page 18 line 5).

However, the terminology of a "dynamically customizable form" does not appear **anywhere** in the portions of the specification provided by the Applicant as support for this limitation. Therefore, it is suggested that the Applicant provide claim language which reflects the terminology found within the specification.

Furthermore, the Examiner respectfully submits that as noted in MPEP § 2111, during patient examination, claims are given their broadest reasonable interpretation consistent with the specification. It is proper to use the specification to interpret what the applicant meant by a word or phrase recited in the claim. However, it is **not** proper to read limitations appearing in the specification into the claim when these limitations are not recited in the claim. See *In re Paulsen,* 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994); *Intervet America Inc. v. Kee-Vet Lab. Inc,* 887 F.2d 1050, 1053, 12 USPQ 2d 1474, 1476 (Fed. Cir. 1989).

Moreover, words of the claim are generally given their ordinary and customary meaning, unless it appears from the written description that they were used differently

by the applicant. Where an applicant chooses to be his or her own lexicographer and defines terms with special meanings, he or she must set out the special definition explicitly and with "reasonable clarity, deliberateness, and precision" in the disclosure to give one of ordinary skill in the art notice of the change. See *Teleflex Inc. v. Ficosa North America Corp.*, 299 F.3d 1313, 1325, 63 USPQ2d 1374, 1381 (Fed. Cir. 2002), *Rexnord Corp. v. Laitram Corp.*, 273 F.3d 1336, 1342, 60 USPQ2d 1851, 1854 (Fed. Cir. 2001), and MPEP § 2111.01. Pursuant to 35 USC § 112, 2nd paragraph "[i]t is applicant's burden to precisely define the invention, and not the [examiner's]." *In re Morris,* 127 F.3d 1048, 1056, 44 USPQ2d 1023, 1029 (Fed. Cir. 1997). Therefore, it would **not** be proper for the examiner to give words of the claim special meaning when no such special meaning has been defined by the applicant in the written description. Furthermore, it would **not** be proper for the examiner to allow a claim and issue the application with an examiner's statement of reasons for allowance setting forth the special definition given to the words of the claim when no such special definition has been defined by the applicant in the written description.

Therefore, Applicant is required to cancel the new matter in the reply to this Office Action.

3. Furthermore, the specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the Applicant uses the terminology of a "dynamically customizable form" throughout the claims. However, the Examiner

was not able to find any mention of the terminology within the specification to support this limitation. Therefore, it is suggested that the Applicant provide claim language which reflects the terminology found within the specification.

4. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. The objection to the specification under 35 U.S.C. § 112, first paragraph, because the specification, as originally filed, does not provide support for the invention as is presently claimed is maintained. Further reasons are given in sections 2-3 above.

Claim Rejections - 35 USC § 112

6. The rejection of claims 21-29 and 31-41 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained, and the reasons are set forth in sections 2-3 above.

7. Independent claims 21 and 33 recite limitations that are new matter, as discussed above.

8. Claims 22-29, 31-32, and 34-41 incorporate the deficiencies of independent claims 21 and 33, through dependency, and are also rejected.

NOTE: For purposes of applying prior art and to the extent that the Examiner understands the specification, in particular page 13 line 5 to page 18 line 24, "a dynamically customizable form" is assumed to be a visit form established and defined by the user selecting a "Visit Form Definition" operation (see page 13 lines 22-23 of the specification) where the user is able to define the form such as procedure and diagnosis column width and sequence based on the user's personal taste and functional arrangement of the actual visit form (see page 15 lines 7-10).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

NOTE: The following rejections assume that the subject matter added in 24 April 2003 amendment are NOT new matter, and are provided hereinbelow for Applicant's consideration, on the condition that Applicant properly traverses the new matter

objections and rejections made in preceding sections above in the next communication sent in response to the present Office Action.

9. Claims 21-29 and 32-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans (5,924,074) in view of Feldon et al. (5,732,221).

(A) As per claim 21- 22, 24-25, and 31-32, Evans discloses a medical records method and system for storage and retrieval of dynamic electronic medical records in a computer environment, such as a local or wide area network including portable computers (col. 1 lines 5-10), wherein patient data, such as patient complaints, lab orders, medications, diagnoses, and procedures, are captured at the point of care of a patient in real-time, such as during an examination or in hospital (see Figure 24), using a graphical user interface having touch screens in a point of care system (Abstract; lines 1-5; col. 2 lines 20-64, col. 5 lines 29-55, and col. 5 lines 8-10), comprising:

(a) entering patient data electronically, wherein the health care provider clicks on a scroll down button to select a form from a list of available forms for entering patient data, wherein a new forms box is activated, wherein the provider then clicks on a new form buttons, and wherein a new form window is then displayed, wherein the health care provider then fills out the form using an input device, such as a keyboard, mouse, or an electronic pen, and wherein the provider then exits the form using the File Menu and the patient record is filed in the patient data repository for future reference (Abstract, lines 1-2; Fig. 5-6, col. 5 lines 28-55, and col. 6 line 55 to col. 7 line 5); and

(b) wherein the patient data entered or selected includes diagnoses and procedures (Fig. 20-21 and col. 6 lines 9-36), including ICD9 diagnosis codes and CPT procedure codes, wherein the procedures are administered to the patient by the health care provider during an examination or in a hospital (Fig. 1, 14, and 24, col. 6 lines 9-26, col. 9 lines 4-13, and col. 11 lines 36-64).

Evans fails to expressly disclose generating a dynamically customizable form, including selecting procedures and diagnoses for inclusion within the form. However, Evans discloses entering patient data through an electronic form as discussed in the above system (Abstract; lines 1-5; col. 2 lines 20-64, col. 5 lines 29-55, and col. 5 lines 8-10). Feldon discloses entering a patient's demographic information, medical history, prescribed medication and other relevant information for a patient, including information a physician documents during the exam using exam descriptors, into data entry forms, wherein a user is able to customize these data entry forms by editing existing forms or by redesigning completely new forms, wherein the form is able to be saved (col. 4 lines 13-63, col. 8 lines 62-67, and col. 9 lines 15-65, col. 11 lines 1-58, and col. 12 lines 1-9).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to include the aforementioned features of Feldon within the method of Evans with the motivation of allowing forms to be generated based on the user's needs and customized for the particular task at hand (Feldon; col. 4 lines 52-54) and transforming a patient chart from a static record of a few clinical interactions into a dynamic, real-time comprehensive record (Evans; col. 2 lines 34-40).

(B) As per claim 23, Evans discloses a data interface permitting communication with external sources to obtain patient data and to transfer patient information to external health care providers, such as demographic data, laboratory test results, x-ray images, ICD9 diagnosis codes and CPT procedure codes, prescriptions for medications (col. 9 lines 1-14). The remainder of claim 23 repeats the same limitations as claim 21, and is therefore rejected for the same reasons given for claim 21, and incorporated herein. It is noted that the step of transferring patient information, including ICD9 diagnosis codes and CPT procedure codes, to external health care providers (col. 9 lines 1-14) is considered to be a form of "one or more other healthcare procedures or diagnoses used by another healthcare provider of a healthcare facility" as recited in claim 23.

(C) As per claim 26, Feldon discloses customizing data entry forms for a physician, for example for an examination of the eye by defining common types of eye exams (col. 1 line 20 to col. 2 line 12 and col. 4 lines 30-45). The remainder of claim 26 repeats the same limitations as claim 21, and is therefore rejected for the same reasons given for claim 21, and incorporated herein. The motivation for combining Feldon within Evans is given above in claim 21, and is incorporated herein.

(D) As per claim 27-29, Evans discloses entering and updating a patient record using a form, wherein the patient record includes insurance information, ICD9 diagnosis codes and CPT procedure codes, wherein upon entering and updating information, the electronic medical record system filed the patient's record in real-time in the patient data

repository (Abstract, lines 1-2; Fig. 2-3, 5-6, and 14, col. 5 lines 1-27, col. 6 line 55 to col. 7 line 5, col. 9 lines 1-14).

It is noted that Evan's discloses recording insurance information as well as diagnosis and procedure codes within a patient record as discussed above (Abstract, lines 1-2; Fig. 2-3, 5-6, and 14, col. 5 lines 1-27, col. 6 line 55 to col. 7 line 5, col. 9 lines 1-14). As this information is most frequently used for billing purposes (i.e., billing insurance companies), it is respectfully submitted that this information within the patient record is a form of a "billing record." Furthermore, as per the recitation of "the billing record corresponding to standards in the industry," it is noted that ICD9 codes and CPT codes are widely accepted codes used to report and index medical records and are considered to be the standard codes set for reporting health care services in electronic data transactions.

(E) Claims 33-38 and 40-41 differ from method claims 21-29 and 31-32 by reciting hardware elements, namely, a computer readable medium and computer program code which is executable. As per these elements, Evans discloses:

(a) a multi-processor personal computer having 20 GB of storage capacity (col. 12 line 66 to col. 13 line 30); and

(b) applications running under Microsoft ® Windows ™ to access data from a variety of data sources (col. 13 line 57 to col. 14 line 25).

The remainder of claims 33-38 and 40-41 repeat the same limitations as claims 21-29 and 31-32, and are therefore rejected for the same reasons given for those claims, and incorporated herein.

Response to Arguments

10. Applicant's arguments filed 24 April 2003 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 24 April 2003.

(A) At pages 12-14 of the 24 April 2003 response, Applicant argues the 35 U.S.C. § 103(a) obviousness rejection is improper because the references are not properly combinable and further teach away from each other.

In response to applicant's argument that the references are not properly combinable, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

In addition, the Examiner respectfully submits that the issue at hand is not whether the applied prior art specifically teaches a dynamically customizable form , *per se*, but rather, whether or not the prior art, when taken in combination with the

knowledge of average skill in the art, would put the artisan in possession of this feature. Regarding this issue, it is well established that references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures, *In re Bozek*, 163 USPQ 545 (CCPA 1969). The issue of obviousness is not determined by what the references expressly state but by what they would reasonably suggest to one of ordinary skill in the art, as supported by decisions in *In re DeLisle* 406 Fed 1326, 160 USPQ 806; *In re Kell, Terry and Davies* 208 USPQ 871; and *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ 2d 1596, 1598 (Fed. Cir. 1988) (citing *In re Lalu*, 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed. Cir. 1988)). Further, it was determined in *In re Lamberti et al*, 192 USPQ 278 (CCPA) that:

(i) obviousness does not require absolute predictability;

(ii) non-preferred embodiments of prior art must also be considered; and

(iii) the question is not express teaching of references, but what they would suggest.

According to *In re Jacoby*, 135 USPQ 317 (CCPA 1962), the skilled artisan is presumed to know something more about the art than only what is disclosed in the applied references. In *In re Bode*, 193 USPQ 12 (CCPA 1977), every reference relies to some extent on knowledge of persons skilled in the art to complement that which is disclosed therein.

According to *Ex parte Berins*, 168 USPQ 374 (Bd. Appeals), there is no statutory limitation as to the number of references that may be used to demonstrate obviousness...not what references expressly state but what they would reasonably

suggest to one of ordinary skill in the art. In *In re Conrad*, 169 USPQ 170 (CCPA), obviousness is not based on express suggestion, but what references taken collectively would suggest.

In this case, Evans discloses a medical records system for storage and retrieval of dynamic electronic medical records including patient data in a form and Feldon discloses entering a patient's demographic information, medical history, prescribed medication and other relevant information for a patient, including information a physician documents during the exam using exam descriptors, into data entry forms, wherein a user is able to customize these data entry forms by editing existing forms or by redesigning completely new forms, wherein the form is able to be saved. It is the position of the Examiner that the skilled artisan would be in possession of a dynamically customizable form, such as that claimed in the amendment filed 24 April 2003, when considering the teachings of Evans and Feldon, collectively, in combination with the knowledge of average skill in the art, for at least the reason that the skilled artisan would readily recognize that allowing forms to be generated based on the user's needs and customized for a particular task at hand (Feldon; col. 4 lines 52-54) allows a user to transform a patient chart from a static record of a few clinical interactions into a dynamic, real-time comprehensive record (Evans; col. 2 lines 34-40).

As such, it is respectfully submitted that Applicant appears to view each of the applied references separately, in a vacuum, without considering the knowledge of average skill in the art, and that such piecemeal analysis is improper.

In response to Applicant arguments that the combination of Evans and Feldon is improper since the rejection is based upon a modification of Evans that destroys the intent, purpose, or function of the invention as disclosed in Evans.

In response, the Examiner submits that the Evans reference does not teach away from the applied combination of references or the Applicant's invention. Evans suggests several advantages that the invention is intended to provide for users, including the ability to transform a patient chart from a static record of a few clinical interactions into a dynamic, real-time comprehensive record (Evans; col. 2 lines 34-40). Contrary to the Applicant's assertion, the proposed modification applied in the rejection of claim 21 does not destroy the intent, purpose, or function of the invention as summarized by the cited passage of Evans.

Moreover, when considering and applying prior art to claim limitations, alternate embodiments may be considered. According to MPEP §2123, "a reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including non-preferred embodiments." *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See also *Celeritas Technologies Ltd. v. Rockwell International Corp.*, 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir. 1998) Evans discloses that "accordingly, the disclosed embodiments of the invention are merely illustrative and do not serve to limit the scope of the invention set forth in the claims..." (col. 15 lines 61-67). The Examiner interprets this phrasing to mean the aspects disclosed and summarized in the passage are parts of a limited or preferred embodiment that does not preclude other possible

embodiments that have alternate configurations that still provide the disclosed advantages of the Evans system.

With respect to the limitations recently added to the claims in the amendment filed 24 April 2003, the Examiner respectfully submits that all features presently claimed in claims 21-29 and 31-41 are disclosed by the collective teachings of the Evans and Feldon references as discussed in detail in sections 9(A)-(E) above in addition to the reasons set forth in the prior Office Action (paper number 7; section 12(A)-(E), pages 5-9), and incorporated herein, provided there is clear support for the newly added features in the specification as originally filed.

(B) Applicant's remaining arguments given at pages 14-16 of the response filed 24 April 2003 rely upon or re-hash the issues addressed above, and are therefore moot in view of the responses given in section 10(A) above, and incorporated herein.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to the Applicant's disclosure. The cited but not applied prior art teaches a clinical critical care path system and method (6,401,072) and a method for facilitating patient care plans (6,434,531).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Bleck whose telephone number is (703) 305-

3981. The Examiner can normally be reached on Monday-Thursday, 8:00am – 5:30pm, and from 8:30am – 5:00pm on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached at (703) 305-9588.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist whose telephone number is (703) 306-1113.

13. **Any response to this action should be mailed to:**

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Or faxed to:

(703) 305-7687	[Official communications; including After Final communications labeled "Box AF"]
(703) 746-8374	[Informal/ Draft communications, labeled "PROPOSED" or "DRAFT"]

Hand-delivered responses should be brought to Crystal Park 5, 2451 Crystal Drive, Arlington, VA, 7th Floor (Receptionist).

CB
July 2, 2003

JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3600